

BEST AVAILABLE COPY

ENTRAL OR ENTERIC COATING AND GELATIN (NOT ENCAPSULATE)

012203359

WPI Acc No: 1999-009465/199901

XRAM Acc No: C99-003264

Oral pharmaceutical dosage form - comprises acid sensitive drug in enteric coated capsule or having protective barrier layer and enteric coating

Patent Assignee: SAGE PHARM INC (SAGE-N)

Inventor: CHEN J

Number of Countries: 080 Number of Patents: 002

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9850019	A1	19981112	WO 98US9449	A	19980508	199901 B
AU 9873755	A	19981127	AU 9873755	A	19980508	199915

Priority Applications (No Type Date): US 97950432 A 19971015; US 9746089 A 19970509

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 9850019 A1 E 27 A61K-009/40

Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GE GH HU IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW

AU 9873755 A A61K-009/40 Based on patent WO 9850019

Abstract (Basic): WO 9850019 A

Oral pharmaceutical dosage form comprises: (a) a core granulation formed by dry mixing an acid-unstable drug or its salt with alkaline substance and at least 1 excipient; (b) a hard gelatin capsule shell into which the granulation or tablet of (a) is filled and (c) an enteric coating on the capsule.

The drug active ingredient preferably comprises omeprazole, sodium omeprazole, potassium omeprazole, calcium omeprazole, ammonium omeprazole or lansoprazole or its salts. The alkaline substance comprises alkali metal salts of carbonic acid, optionally granulated calcium carbonate, anhydrous dicalcium phosphate, anhydrous dibasic sodium phosphate, anhydrous tricalcium phosphate, sodium carboxymethylcellulose, calcium, carboxymethylcellulose, magnesium aluminium silicate, sodium lauryl sulphate or sodium bicarbonate. The excipient comprises at least 1 of dextrose, sorbitol, mannitol, starch, dextrin, maltodextrin, lactose, magnesium and calcium stearates, talc, microcrystalline cellulose, HPMC and hydroxyethyl cellulose.

ADVANTAGE - The drug is protected from the attack of acidic gastric fluid and is efficiently delivered to the small intestine. The form is economical in terms of time, process and material savings compared with known forms and is sufficiently stable for commercial distribution and storage. The enteric coating prevents the drug being released in the gastric environment and delivers it in the intestinal environment.